

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
v.)	C.A. No. 21-1015 (JLH)
SAREPTA THERAPEUTICS, INC., Defendant.)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs,)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
v.)	
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter-Defendants.)	

**NS’S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS RESPONSE
TO SAREPTA AND UWA’S MOTION FOR SUMMARY JUDGMENT NO. 3
OF NO INEQUITABLE CONDUCT AND NO *WALKER* PROCESS FRAUD**

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Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: January 12, 2024

1. U.S. Patent Nos. 9,994,851 (“the ’851 patent”), 10,227,590, and 10,266,827 (collectively, the “UWA Patents”) (Sarepta Exs. 1-3) have substantively identical specifications and claim priority to PCT/AU2005/000943 (“the 2005 PCT”) (Sarepta Ex. 11), the disclosure of which is substantively identical.

2. The 2005 PCT was filed on June 28, 2005. Sarepta Ex. 11.

3. Stephen Wilton and Sue Fletcher were involved in [REDACTED]
[REDACTED]. NS Ex. 38, Wilton Dep. 67:25-68:3; NS Ex. 39, Fletcher Dep. 63:20-23.

4. Table 39 in the UWA Patents’ specification was first disclosed in the 2005 PCT.

5. The 2005 PCT and the UWA Patents’ specification state that the antisense oligonucleotides (“AOs”) in Table 39 were “tested at a concentration range of 50, 100, 300 and 600 nM” with the exception of one AO that was “not made yet.” Sarepta Ex. 1, ’851 patent Col. 64:46-47; Table 39.

6. The 2005 PCT and the UWA Patents’ specification describes SEQ ID NO: 195 as a 2’-O-methyl phosphorothioate (“2-O-methyl”) antisense oligonucleotide targeting H53A(+23+47). Sarepta Ex. 1, ’851 patent, Table 39 and Col. 133-135.

7. Table 39 provides reports on the listed AOs’ “ability to induce skipping” and that testing of SEQ ID NO: 195 showed “Very faint skipping to 50 nM.” Sarepta Ex. 1, ’851 patent, Table 39.

8. According to Sarepta’s experts, the written description support for the limitation “induces exon 53 skipping” in the claims of the UWA Patents is found in Table 39. NS Ex. 8, Hirshfeld Report at 34 (citing Dowdy Report ¶ 117); NS Ex. 40, Hirshfeld Dep. 126:18-128:12 (discussing same).

9.

NS Ex. 41, Notebook, SRPT-VYDS-0156085; NS Ex. 42,

Notebook, SRPT-VYDS-0158109.

10.

NS Ex. 43, Notebook, SRPT-VYDS-0155714 at

754.

11.

NS Ex. 43,

SRPT-VYDS-0155714 at 754; NS Ex. 44, FLETCHER0000226 at 250 (

12.

Ex. 41, SRPT-

VYDS-0156085 at 088-89, 166, 172.

13.

NS Ex. 41, SRPT-VYDS-

0156085 at 088, 166, 172.

14.

NS Ex. 41,

SRPT-VYDS-0156085; NS Ex. 42, SRPT-VYDS-0158109; NS Ex. 45, SRPT-VYDS-0158291.

15.

NS Ex. 41, SRPT-VYDS-0156085; NS Ex. 42, SRPT-VYDS-

0158109; NS Ex. 45, SRPT-VYDS-0158291.

16.

NS Ex. 41,

SRPT-VYDS-0156085 at 089, 265, 268, 273.

17. [REDACTED]

[REDACTED] NS Ex. 41,
SRPT-VYDS-0156085 at 089, 268-273.

18. [REDACTED]

[REDACTED] NS Ex. 45, SRPT-VYDS-
0158291 at 316-318.

19. [REDACTED]

[REDACTED] NS Ex. 46, [REDACTED]
Dep. 37:14-24, 38:17-20; NS Ex. 47, [REDACTED] Book [REDACTED], SRPT-VYDS-0163133 at
231, 233 and 261, 284.

20. Harding et al., Mol. Ther. 15(1):157-166 (2007) (“Harding 2007”) is an article by
Wilton and Fletcher published in January 2007. Sarepta Ex. 55.

21. Harding 2007 was published after the claimed priority date of the UWA Patents.

22. The AOs studied in Harding 2007 include SEQ ID NO: 195. Sarepta Ex. 55,
Harding 2007 at 159, Table 1 (listing H53A(+23+47)).

23. Harding 2007 states “amenable sites to redirect dystrophin splicing were
identified at... 39-69 bases within the 212 base long exon 53.” Sarepta Ex. 55, Harding 2007 at
164.

24. Harding 2007 was disclosed to the PTO during prosecution of each UWA Patent
in Information Disclosure Statements that each disclosed over a thousand other references.
Sarepta Ex. 14 at SRPT-VYDS-0003124-187; Sarepta Ex. 15 at SRPT-VYDS-0005451-608;
Sarepta Ex. 16 at SRPT-VYDS-0006280-465.

25. [REDACTED]

[REDACTED] NS Ex. 38, Wilton Dep. 27:18-28:18; NS Ex. 39, Fletcher Dep. 208:7-10.

26. [REDACTED]

[REDACTED] NS Ex. 38, Wilton Dep. 27:18-28:18; NS Ex. 39, Fletcher Dep. 208:7-10.

27. [REDACTED]

[REDACTED] NS Ex. 38, Wilton Dep. 30:5-14; NS Ex. 39, Fletcher Dep. 122:5-9, 125:21-126:5.

28. [REDACTED]

[REDACTED] NS Ex. 38, Wilton Dep. 30:5-14; NS Ex. 39, Fletcher Dep. 122:5-9, 125:21-126:5.

Dated: January 12, 2024

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CERTIFICATE OF SERVICE

I, Amy Dudash, certify that on January 12, 2024, I caused a copy of the foregoing document which was filed under seal, to be served via electronic mail on the following counsel of record:

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